

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address COMMISSIONER FOR PATENTS FO Box 1430 Alexandria, Virginia 22313-1450 www.tepto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,279	03/18/2004	M. David Butts	1016720023P	5654
34284 7590 04/02/2009 Rutan & Tucker, LLP. 611 ANTON BLVD			EXAMINER	
			BOUCHELLE, LAURA A	
SUITE 1400 COSTA MESA	A, CA 92626		ART UNIT	PAPER NUMBER
			3763	
			MAIL DATE	DELIVERY MODE
			04/02/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 10/803 279 BUTTS ET AL. Office Action Summary Examiner Art Unit LAURA A. BOUCHELLE 3763 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status Responsive to communication(s) filed on 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims Claim(s) is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) _____ is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

1) Notice of References Cited (PTO-892)

Paper No(s)/Mail Date ___

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (PTO/SB/08)

Interview Summary (PTO-413)
Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application

Application/Control Number: 10/803,279 Page 2

Art Unit: 3763

DETAILED ACTION

In response to the Amendment After Final filed 11/24/08 a new search was conducted and new prior art was discovered. Prosecution has been reopened and a new non final action on the merits follows

Claim Rejections - 35 USC § 103

- The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 2. Claims 2, 3, 5, 7,8, 10, 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cosentino et al (US 4123091) in view of Dennehey et al (US 4340052) in view of Tucker (US 4539003). Cosentino discloses a connector comprising a body 11 having a cannula 15 and a tail 12, the cannula having a blunt distal end for insertion into the proximal end of a catheter 26, the tail configured for insertion into the distal end of a tube 20, and a securement device 16. The body comprises a ribbed region 13 that may also be considered to be a barbed end. The body comprises a head 14, the cannula extending therefrom.
- 3. Claims 14 differ from Cosentino in calling for the securement device to have mating portions that lock together around the catheter. Dennehey teaches a connector 20 for connecting a catheter 22 to a tube 16, and further including a securement device 24 which has mating portions that lock around the catheter. The securement device has a living hinge. This securement device performs a similar function to that of the securement device of Cosentino, to ensure a secure connection between the two components to prevent accidental uncoupling and to allow for quick release. The device of Dennehey further allows for an antiseptic to be applied to the connection point to prevent any contamination. Therefore, it would have been obvious to

Art Unit: 3763

substitute the securement portion of Dennehey for the securement portion of Cosentino because they are analogous components that perform the same function equally well, but the securement device of Dennehey has the further benefits of keeping the connection point sterile.

- 4. Claims 14 further differ from the teachings above in calling for a winged apparatus positioned over at least a portion of the body. Tucker teaches a winged apparatus for clamping over tubing coupler to prevent separation; the wings 4 extend the clamp for easier application and removal of the device (Col. 2, lines 35-36). The winged apparatus has ridges 3 that mesh with the outer contours of the connector to grasp the device (Col. 2, lines 32-34). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the securement device of Dennehey to include the wings as taught by Tucker to allow for easy gripping of the connector for easier application and removal of the device.
- 5. Claim 15 calls for the winged apparatus to be formed of silicone. Tucker discloses that the winged apparatus is formed of a flexible material. It is known in the art to use silicone for flexible medical devices that will contact the skin of a patient because it is biocompatible, sterilizable, and durable. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Tucker to be formed of silicone because it is a known biocompatible and durable material.
- 6. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cosentino in view of Dennehey in view of Tucker in view of Godeau et al (US 6155610). Claim 6 differs from Cosentino in calling for the cannula to be formed of metal. Godeau teaches a connector wherein the components may be formed of a suitable metal because metal is durable and sterilizable.

Application/Control Number: 10/803,279 Page 4

Art Unit: 3763

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Cosentino to include a cannula comprised of metal because Godeau teaches that it is known to form portions of a connector device of metal because metal is durable, easily machined, and sterilizable.

- Claims 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cosentino et al (US 4123091) in view of Dennehey et al (US 4340052).
- 8. Claims 20 differ from Cosentino in calling for the securement device to have mating portions that lock together around the catheter and include gripping liners. Dennehey teaches a connector 20 for connecting a catheter 22 to a tube 16, and further including a securement device 24 which has mating portions that lock around the catheter and has a gripping liner (col. 4, lines 18-25). The securement device has a living hinge. This securement device performs a similar function to that of the securement device of Cosentino, to ensure a secure connection between the two components to prevent accidental uncoupling and to allow for quick release. The device of Dennehey further allows for an antiseptic to be applied to the connection point to prevent any contamination. Therefore, it would have been obvious to substitute the securement portion of Dennehey for the securement portion of Cosentino because they are analogous components that perform the same function equally well, but the securement device of Dennehey has the further benefits of keeping the connection point sterile.

Allowable Subject Matter

Claims 21-25 are allowed.

Application/Control Number: 10/803,279

Art Unit: 3763

10. Claims 11, 18, 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA A. BOUCHELLE whose telephone number is (571)272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura A Bouchelle Examiner Art Unit 3763 Application/Control Number: 10/803,279 Page 6

Art Unit: 3763

/Nicholas D Lucchesi/ Supervisory Patent Examiner, Art Unit 3763